MSP AG: Data Analytics

Update on EU clinical trials metrics

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Key Performance Indicators

Monitoring CT environment

- **Aim:** Monitor the clinical trial environment to render the EU a favourable environment for clinical research
- Three overarching benefits identified:
- **KPI 1 Attractiveness:** Number of authorised multinational clinical trials
- **KPI 2 Time/speed:** Recruitment of patients at the first MSC within/less 200 calendar days since CTA submission
- KPI 1 and KPI 2 have been endorsed by the network including ACT EU SG, discussed at HMA/MB, will be measured in the next 5 years against defined targets and complemented by sub-metrics
- Measurement will start from 2026, with figures regularly disclosed on the ACT EU website
- **Impactfulness**, endorsed in April 2025, will be a composite approach with no a single KPI but several sub-metrics

Additional sub-metrics

Increased attractiveness

- Global trend on clinical trials in other regions
- Analysis of commercial/non-commercial sponsors per Member State
- Number of patients in the EU* *vs* number of patients worldwide
- Number of Scientific Advice in correlation with Request for Information (RFI)
- Number of first-in-human and/or first-in-class and Phase I studies

Faster access to treatment

- Time from submission of CTA to authorisation
- Time from start of recruitment to end of recruitment and end of trial
- Time from submission to the start of recruitment per Member State
- Time from submission of the CTA to end of trial
- Measuring estimated duration of trial *vs* real duration
- Time needed to stipulate site contracts
- Time between end of trial and a Marketing Authorisation Application (MAA)

For measurement on quarterly basis

**for consideration further stratification of parameters per mono/multi, trial phase, therapeutic area*

Parameters to measure as indication of impactful clinical trials	
Number of EU clinical trials that reach a marketing authorisation (MA) dossier	Quarterly
Proportion of EU clinical trial in MA dossier submitted to the centralised marketing authorisation procedure	Quarterly
Estimated number of EU trial participants in CTA (breakdown clinical trials phase and population age)	Quarterly
Number of clinical trials in paediatric population (detailed breakdown per age range) and if the trial was included in a PIP	Quarterly
Number of EU clinical trials per gender and vulnerable population	Quarterly
Number of EU clinical trials with a medical device	Quarterly
Number of EU clinical trials with an ATMP (per ATMP type) – *innovative treatment*	Quarterly
Number of EU clinical trials to treat rare disease	Quarterly
Number of EU clinical trials with summary of results	Quarterly
Number of EU clinical trials that are early terminated	Lower priority - quarterly

3-Year analysis report

- Report focused on clinical trials data submitted in CTIS during the transition period, covers January 2022- January 2025
- Shows that 2022 has been a year of adaptation for the sponsors and for the network to new legal requirements of the CTR
- Trend of new clinical trial applications has increase steadily from 2023 till now
- Successful transition of more than 5,000 clinical trials to CTIS
- Number of multinational clinical trials stable compared to CTD data
- Activities are in place under ACT EU and other initiatives (e.g., CTR Collaborate) to address the main points raised related to operational aspects of CTR implementation
- Continuous enhancement of CTIS to improve user's experience

Publication of KPIs and 3-year report

- **News:** Launch of new KPIs with targets to monitor EU CT environment, complemented by the publication of the 3-year report on CTR implementation
- **Overview of communication activities:**
- News announcement on 22 September
- LinkedIn live event with EMA, COM and HMA representative on 24 September
- **Start measuring from January 2026**
- Publication on ACT EU website (Homepage and in the quarterly reports (PDF) accessible under the page *Implementation of the CTR)*

Thank you

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